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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/235,875	01/22/1999	LARA MADISON	MBX020	2296
23579	7590	02/02/2005	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 02/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/235,875	<b>Applicant(s)</b> MADISON ET AL.	
	<b>Examiner</b> Russell Kallis	<b>Art Unit</b> 1638	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 20 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 20 January 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1, 6, 7, 10 and 14-21.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

Continuation of 11. does NOT place the application in condition for allowance because:

The rejection under 35 USC 112 1st paragraph, NEW MATTER, that the specification does not support the amendment filed February 3, 2004, which recites "a phbC polymerase gene that encodes an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl-CoA", is maintained for reasons of record.

Applicant asserts that Examples 2, 3 and 5 and the sequence of Figure 9 are drawn to the the PHA synthase gene (phaC) from *A. caviae* and *P. putida* and thus support for a phbC polymerase gene that encodes an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl-CoA.

There is nothing in the specification or originally filed claims that asserts that there is an isolated phbC gene encoding an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl-CoA. Applicant's arguments have not addressed the new matter rejection because they are directed to genes other than a phbC gene. Applicant is arguing limitations that are not in the claims. Examples 2, 3 and 5 and the sequence shown in Figure 9 are drawn to the PHA synthase gene (phaC) from *A. caviae* and *P. putida*.

The rejection under 35 USC 112 1st paragraph, written description, that the specification does not adequately describe genes encoding enzymes set forth in the claims; namely a phbA thiolase gene, a phbB reductase gene, a phbC polymerase gene encoding an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl CoA; a gene encoding a b-hydroxyacyl-ACP-coenzyme A transferase, a D-specific enoyl-CoA hydratase, a thiolase specific for 3-ketohexanoyl CoA, a reductase specific for 3-ketohexanoyl and one or more fatty acid biosynthetic enzymes is maintained.

Applicant asserts that the sequence information can be obtained from publications cited on pages 1 and 2 of the specification and are commercially available (response page 7).

Only references authored by Steinbuchel and the U.S. Patents of Peoples and Sinskey listed on page 2 of the response collectively describe phbCAB genes from *A. eutrophus*, a PHA polymerase gene (phaC) from *Nocardia salmonicolum*, a phaC and phbC gene from *P. oleovorans*, and a phbAB gene from *Zoogaea ramigera*.

Applicant asserts that they have sent results of GenBank searches for phbB, phbA and phbC (response page 7).

The submission dates for those sequences are after the effective filing date of January 22, 1998.

Applicant asserts that they have sent results of GenBank searches for acyl CoA synthase, acyl ACP thioesterase and ACP-CoA transacylase sequences published before the January 22, 1998 priority date of the instant application (response page 7).

The Examiner acknowledges Applicant's evidence for the claimed fatty acid biosynthetic genes prior to the effective filing date, however the rejection is maintained for the reasons set forth above.

Applicant asserts that one of ordinary skill would know how to isolate each of the genes of the claimed methods (response page 7-10).

The ability to isolate a gene does not adequately describe the gene or pointing to an organism that has the activity of one of the gene products of the invention does not demonstrate possession considering that one would have to isolate that gene and then confirm that it has the claimed activity. Moreover, Applicant's submission of sequences in their responses combined with the teachings in the specification of genes encoding PHA synthase from *A. caviae* (phaC), and  $\beta$ -ketoacyl-CoA reductase (phbB) and  $\beta$ -ketothiolase (phbA) from *R. Eutropha* does not describe a representative number of sequences that describe a genus of the broadly claimed phbA thiolase gene, phbB reductase gene, and especially the genus of "a phbC polymerase gene encoding an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl CoA", of which none are described in this application; see arguments supra,

In addition, Applicant has not revealed the commercial sources for the claimed genes, but merely speculates by reciting "such as the ATCC".

The rejection under 35 USC 112 1st paragraph, lack of enablement, that the specification is enabling for a method of production of a polyhydroxyalkanoate containing 3-hydroxyhexanoate, by growing a bacterium transformed with a phaC gene from *A. caviae*, a phbA from *R. Eutropha* and a phbB gene from *R. Eutropha*; or by growing a bacterium transformed with a phaB gene from *R. Eutropha* and a phaJ gene from *A. caviae*, does not reasonably provide enablement for a method of production of a polyhydroxyalkanoate containing 3-hydroxyhexanoate, comprising providing a bacteria expressing a phbA thiolase gene, a phbB reductase gene, and a phbC polymerase gene encoding an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl CoA; further comprising a gene encoding a b-hydroxyacyl-ACP-coenzyme A transferase; or further comprising a phaJ gene encoding a D-specific enoyl-CoA hydratase; or further comprising the genes encoding the enzymes of Claim 17; or further comprising expressing genes encoding one or more fatty acid biosynthetic enzymes is maintained.

Applicant's asserts that there is adequate support in the

specification for all of the claimed genes and enzymes, that they mat

be isolated, or they have been described in publications or they may be purchased from commercial sources (response page 12) and asserts that they have provided numerous working examples (response pages 12-13).

Applicants arguments are largely duplicative of arguments presented earlier in previous office actions and have already been addressed.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

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SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600